

Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA

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**This document supersedes “Class II Special Controls Guidance Document:
Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis;
Draft Guidance for Industry and FDA” dated September 6, 2001.**



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Orthopedics Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation**

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket Number: 01D-0318 and the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Mr. John S. Goode at (301) 594-2036 or by email jsg@cdrh.fda.gov.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Background

This guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis into class II. The device, as classified, is intended for replacement of a hip joint. This guidance will be issued in conjunction with a Federal Register notice announcing the reclassification of this device type.

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the hip joint metal/polymer constrained cemented or uncemented prosthesis. Thus, a manufacturer who intends to market a device of this generic type should (1) conform with the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with the hip joint metal/polymer constrained cemented or uncemented prosthesis identified in this guidance, and unless exempt from the premarket notification requirements of the Act, (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification, product code, and classification identification for the hip joint metal/polymer constrained cemented or uncemented prosthesis. In addition, it lists the risks to health identified by FDA and serves as the special control that, when followed and combined with the general controls, will generally address the risks associated with this generic device type and lead to a timely 510(k) review and clearance. For the specific content requirements of a 510(k) submission, you should refer to 21 CFR 807.87 and other agency documents on this topic, such as **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, <http://www.fda.gov/cdrh/manual/510kprt1.html>.

Device manufacturers may submit an Abbreviated 510(k) when: (1) a guidance document exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard. FDA believes an Abbreviated 510(k) is the least burdensome means of demonstrating

substantial equivalence once a Class II Special Controls Guidance Document has been issued. See also **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>.

An Abbreviated 510(k) submission should include the required elements identified in 21 CFR 807.87, including a description of the device, the intended use of the device, and the proposed labeling for the device. An Abbreviated 510(k) should also include a summary report. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g).

The summary report should briefly describe the methods or tests used and the acceptance criteria applied to address the risks identified in this guidance document as well as any additional risks specific to your device. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize the particular deviation. The summary report should also either (1) briefly present the data resulting from each test in tabular form or (2) describe the acceptance criteria to be applied to the test results. (See also 21 CFR 820.30 Subpart C Design Controls for the Quality System Regulation.)

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the “**A Suggested Approach to Resolving Least Burdensome Issues**” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

2. Scope

The scope of this document is limited to the hip joint metal/polymer constrained cemented or uncemented prosthesis, regulation number 21 CFR §888.3310, and product code KWZ.

§888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

- (a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys.

This generic type of device is intended for use with or without bone cement (21 CFR §888.3027).

- (b) *Classification.* Class II (special controls). This special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.”

3. Risks to Health

FDA has identified the risks to health generally associated with the use of the hip joint metal/polymer constrained cemented or uncemented prosthesis in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. The 510(k) should describe the risk analysis method. The measures recommended to mitigate the identified risks are given in this guidance document, as shown in the table below. (If a manufacturer elects to use an alternative approach to address a particular risk or has identified risks additional to those in the guidance, you should provide sufficient detail to support the alternative approach.)

Identified risk	Recommended mitigation measures
Infection	Section 6
Adverse tissue reaction	Section 7
Pain and/or loss of function	Sections 7 and 8
Revision	Sections 7 and 8

4. Controls

FDA believes that the measures in the following sections of this guidance, when combined with general controls, will address the identified risks to health associated with the use of the hip joint metal/polymer constrained cemented or uncemented prosthesis. You should demonstrate that your device complies with either the specific recommendations of this guidance or with an alternate means to address the above identified risks and to provide reasonable assurance of the safety and effectiveness of the device. If you have identified any additional risks, specific to your device, your 510(k) should identify those risks, as well as the methods or tests used and the acceptance criteria applied to address them.

5. Abbreviated 510(k) Content

An Abbreviated 510(k) that relies on a Class II Special Controls Guidance Document should contain the following.

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of the specific Class II Special Controls Guidance Document.

Items Required Under 21 CFR 807.87

The items required under 21 CFR 807.87 are:

- **Description of the device and its intended use.** The description should include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. You should also submit an "indications for use" enclosure. See <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.
- **Proposed labeling.**
- **Summary report.** A summary report should describe how the Class II Special Controls Guidance Document was used to address the risks associated with the particular device type. The summary report should contain:
 - Risk analysis.
 - Description of device performance requirements.
 - Discussion of the features and functions provided to address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.
 - For each performance aspect identified in Sections 6-7 of this Class II Special Controls Guidance document, you should briefly discuss each test method and identify your acceptance criteria. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize the particular deviation. The summary report should also either (1) briefly present the data resulting from each test in tabular form or (2) describe the acceptance criteria to be applied to the test results. If any test article does not meet the identified acceptance criteria, you may not market your device. Instead, you must submit a new 510(k) with revised acceptance criteria, 21 CFR 807.81(a)(3). The new 510(k) must be cleared by FDA before you market your device, 21 USC 513(i)(1)(A).

- If any part of the device design or testing relies on a recognized standard, the summary report should include: (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.¹ Testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information, see FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or by your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information, if we need it to assess the adequacy of your acceptance criteria.

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions.

6. Sterility

You should evaluate the sterility of your device according to **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>.

Your summary report should contain the following information for devices sold as sterile:

- the sterilization method used in the sterilization cycle (e.g., dry heat, ethylene oxide (EtO), steam, radiation);
- a description of the method that will be used to validate the sterilization cycle (but not the validation data);
- a description of the packaging that maintains the device's sterility (but not the package integrity testing data);
- the sterility assurance level specification (SAL);²
- a description of the method used to make the determination, e.g., the limulus amebocyte lysate (LAL) method, if the product is labeled pyrogen free;
- the maximum levels of EtO and ethylene chlorhydrin residues, if sterilized by EtO; and

¹ See Required Elements for a Declaration of Conformity to a Recognized Standard (SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS), <http://www.fda.gov/cdrh/ode/regrecstand.html>.

² FDA recommends 10^{-6} for all sterile devices, except sterile devices that only contact intact skin. These should be 10^{-3} .

- the radiation dose, if sterilized by radiation.

7. Material and Performance Characteristics

You should use the applicable FDA guidance documents and consensus standards listed below to establish the material and performance characteristics of your device.

A. FDA Guidance Documents

- “Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement” <http://www.fda.gov/cdrh/ode/827.html>
- “Guidance Document for Testing Non-articulating, ‘Mechanically Locked’ Modular Implant Components” <http://www.fda.gov/cdrh/ode/916.html>
- “Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices-The Basic Elements” <http://www.fda.gov/cdrh/ode/832.html>
- “Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices” <http://www.fda.gov/cdrh/ode/180.html>
- “Draft Guidance Document for Femoral Stem Prostheses” <http://www.fda.gov/cdrh/ode/187.html>
- “Draft Guidance Document for Testing Acetabular Cup Prostheses” <http://www.fda.gov/cdrh/ode/453.html>

B. American Society for Testing and Materials (ASTM) Consensus Standards

- F 67-00, “Standard Specifications for Unalloyed Titanium for Surgical Implant Applications”
- F 75-98, “Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)”
- F 86-01, “Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants”
- F 90-97, “Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)”
- F 136-98, “Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications”
- F 138-00, “Standard Specification for Wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)”
- F 562-00, “Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications”
- F 620-00, “Standard Specification for Titanium-6 Aluminum-4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)”
- F 648-00, “Standard Specification for Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants”

- F 745-00, "Standard Specification for 18 Chromium – 12.5 Nickel 2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications"
- F 746-87 (99), "Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials"
- F 799-99, "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)"
- F 983-86 (2000), "Standard Practice for Permanent Marking of Orthopedic Implant Components"
- F 1044-99, "Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings"
- F 1108-97a, "Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Casting for Surgical Implants (UNS R56406)"
- F 1147-99, "Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings"
- F 1160-00, "Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings"
- F 1377-98a, "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)"
- F 1440-92 (97), "Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion"
- F 1472-00, "Standard Specification for Wrought Titanium – 6 Aluminum – 4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)"
- F 1537-00, "Standard Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants"
- F 1580-95, "Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants"
- F 1612-95, "Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion"
- F 1814-97a, "Standard Guide for Evaluating Modular Hip and Knee Joint Components"
- F 1820-97, "Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device"
- F 1854-98, "Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants"
- F 1978-99, "Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser"

C. International Organization for Standardization (ISO) Consensus Standards

- ISO 5832-1997, "Implants for Surgery - Metallic Materials - Part 1: Wrought Stainless Steel"
- ISO 5832-1996, "Implants for Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy"
- ISO 5832-1996, "Implants for Surgery - Metallic Materials - Part 4: Cobalt-Chromium-Molybdenum Casting Alloy"
- ISO 5832-1992, "Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel"

- ISO 7206-1989, “Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 4: Determination of Endurance Properties of Stemmed Femoral Components with Application of Torsion”
- ISO 7206-1995, “Implants for Surgery Partial and Total Hip Joint Prostheses - Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion”

8. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. The following suggestions are aimed at assisting you in complying with 21 CFR 801 and 21 CFR 801.109.

Prescription Use

In accordance with 21 CFR 801.109, this device must bear the following caution statement: “Caution: Federal law restricts this device to sale by or on the order of a physician.”

Package Insert and Surgical Technique

The package insert and surgical technique should include the following:

Intended Use/ Indications for Use

The hip joint metal/polymer constrained cemented or uncemented prosthesis is intended to replace a hip joint.

The device is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Precautions

In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

To correctly position the metallic locking ring, surgeons should consult the manufacturer’s instructions for appropriate device assembly.

Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.

9. Investigational Device Exemptions

Clinical design validation studies conducted after FDA determines that the device is substantially equivalent are exempt from investigational device exemptions (IDE) requirements in accordance with 21 CFR 812.2(c)(2). However, such studies must be performed in conformance with 21 CFR parts 50 and 56.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the IDE regulation (21 CFR 812). FDA has determined this device is a significant risk device as defined in 21 CFR 812.3(m)(4) and, therefore, studies involving these devices do not qualify for the abbreviated IDE requirements of 21 CFR 812.2(b). In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR 56) and informed consent (21 CFR 50).